Minutes of Meeting

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

May 26, 2004
1:00 p.m.

Attendees: Richard Freeman, Chair; Rob Colburn, Jackie Feldman, David Herrick, A.Z. Holloway, Mary McIntyre, Ben Main, Melanie Smith, Jefferson Underwood, Louise Jones, Janelle Sheen, Robert Berringer

Absent: Garry Magouirk

(1) Opening Remarks
Richard Freeman called meeting to order and asked that all cell phones and pagers be placed in the off position.

(2) Minutes from March 24, 2004 meeting were approved, motion was extended by Rob Colburn and seconded by A.Z. Holloway.

(3) Louise Jones announced changes in the P&T meeting format:

Louise Jones announced that the pharmaceutical manufacturers would provide oral presentations immediately prior to each respective drug class reviews. After the oral and drug class review presentation, the P&T Committee may discuss the review then vote.

The presentation time for pharmaceutical manufacturers during the Pharmacy and Therapeutics Committee meetings has been changed from five minutes to three minutes. Presenters will hear a bell with one minute remaining and will be disallowed from speaking after the three-minute allotment.

Ms. Jones also introduced Janelle Sheen, Pharmacotherapy Specialist with Heritage Information Systems, Inc. Janelle will be responsible for presenting each drug class review.

(4) PHARMACOTHERAPY REVIEWS (Refer to the web for full text reviews):
Section I. Antidiabetic Agents (AHFS Classes 682002, 682004, 682008, 682016, 682020, 682028)

Oral Presentations by Manufacturers/Manufacturer's Representatives and Drug Class reviews began at 1:15 p.m. Three-minute verbal presentations were made on the following drugs by, or on behalf of, the following Pharmaceutical Manufacturers:

Product
Lantus
Actos

Janelle Sheen began the Drug Class Reviews with a reminder that within the Table of Contents, Appendix 1 (i.e., Previous Reviews for Reference) does not have page number references. Additionally, Riomet is included on page 13 of the Antidiabetic Drug Class Review but is currently not eligible for review due to a December 2003 availability date but will be presented at the next P&T Committee meeting. Dr. Underwood questioned as to Fortamet's status and Janelle responded that this medication will also be reviewed at the next meeting.

Janelle began the Antidiabetic Agent review with the α-Glucosidase Inhibitor review. She stated that there are two agents available in this class and neither is generically available. Due to their mechanism of action, they have a relatively high incidence of gastrointestinal adverse drug events. While both agents have similar indications for type 2 diabetes, acarbose is also indicated as combination treatment with either metformin or insulin. Acarbose prescribed at doses greater than 100mg/day may be associated with increased liver function test results. Currently there are no head to head trials comparing these two agents. All brand products within the α - glucosidase inhibitor class are comparable to each other and offer no significant clinical advantage over other alternatives in general use. No brand α - glucosidase inhibitor is recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the biguanides which includes the metformin products and reiterated that due their recent approval and release, both Riomet and Fortamet were not included in this current review but will be reviewed at a subsequent P&T Committee meeting. While the immediate release product is generically available, the extended release product is not. Compared to the extended release product, the immediate release product has a higher incidence of gastrointestinal-related adverse drug events. Both products have similar efficacy. All brand products within the class reviewed are comparable to each other and to the generics in this class and offer no significant clinical advantage over other alternatives in general use. No brand biguanide is recommended for preferred status.

Jackie Feldman commented that in the real world (i.e., clinical practice), the adherence rates with the extended release product are probably higher than the immediate release product due to the lower gastrointestinal adverse events. A.Z. Holloway also commented on this and agreed with Jackie Feldman. Additionally, Jefferson Underwood commented on the potential cost and affordability advantages of administering drugs less frequently. Louise Jones reminded Jefferson Underwood that these reviews are based on clinical information and cost issues are not considered. Mary McIntyre asked if there were any studies

that reported convenience dosing for this class had better outcomes. Janelle responded that at the time of the review, none were available.

A.Z. Holloway made motion to amend the ballot and add metformin extended release as a preferred drug that was seconded by Jackie Feldman. Richard Freeman asked the Board to note the recommendations and mark their ballots.

Janelle Sheen discussed the Insulins and commented that glulisine was released in April 2004 and is not included in this current review. The DCCT (Diabetes Control and Complications Trial) reported that when intensive insulin treatment is started early in patients with type 1 diabetes, the rate of progression of diabetic complications (i.e., retinopathy and nephropathy) is less compared to that among the conventional treatment group. All brand products within the class are comparable to each other and offer no significant clinical advantage over other alternatives in general use. Alabama Medicaid should work with the manufacturers of insulins on cost proposals so that at least one brand is selected as a preferred agent.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the meglitinides including repaglinide and nateglinide and neither are currently available in generic formulations. Both have similar indications but repaglinide is also indicated as combination therapy with the thiazolidinediones. There are differences in the incidence of hypoglycemia with repaglinide (31.0%) and nateglinide (2.4%) but no differences in efficacy. All brand products within the meglitinide class are comparable to each other and offer no significant clinical advantage over other alternatives in general use. No brand meglitinide is recommended for preferred status.

Jackie Feldman asked her colleagues if the hypoglycemia difference is clinically significant in the real world. Jefferson Underwood responded that he knew of no difference in the real world.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the first and second generation sulfonylureas. All the first generation agents and except for glimepiride, all of the second generation agents are available generically. There was no significant difference between agents. Glimepiride was comparable to glyburide and glipizide in glucose control in one study. All brand products within the class reviewed are comparable to each other and to the generics in the sulfonylurea class and offer no significant advantage over other alternatives in general use. No brand sulfonylurea is recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the thiazolidinediones and that none are generically available. Pioglitazone is a weak inducer of cytochrome P450 3A4 substrate while rosiglitazone does not effect this isoenzyme system. No head to head trials have been conducted. Effects on diastolic blood pressure, cholesterol levels and hypoglycemia incidence are improved with the thiazolidinediones than other antidiabetic agents. These agents also have added benefit when used as combination therapy with other antidiabetic agents. The drugs within the thiazolidinedione class offer significant clinical advantage in general use but are comparable to each other. Medicaid should work with manufacturers of pioglitazone (Actos®) and rosiglitazone (Avandia®) on cost proposals so that at least one brand of pioglitazone or rosiglitazone is selected as a preferred agent.

Jackie Feldman asked if patients would have to switch therapy if they were stabilized on a thiazolidinedione agent whose status if non-preferred or could they continue on their current therapy. Mary McIntyre explained this could be considered in criteria development. Jackie Feldman voiced concern about switching patients already stable.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the antidiabetic combination agents and that none are currently available generically. All brand products within the class reviewed are comparable to each other and offer no significant advantage over other alternatives in general use. No brand combination diabetes agent is recommended for preferred status.

Jefferson Underwood commented that due to the four-brand limit implementation, these drugs offer a benefit to patients and to Medicaid. Robert Berringer added that if the separate medications were prescribed, this would only add one additional brand medication. Metformin immediate release is available as a generic and would not be considered in the four-brand limit count. Therefore, there is no true benefit to using the combination treatments over the separate therapeutic entities.

Richard Freeman asked the Board to mark their ballots.

(5) PHARMACOTHERAPY REVIEWS (Refer to the web for full text reviews): Section II. Alzheimer's Agents (AHFS Class 120400).

<u>Product</u>
Aricept, Exelon, Reminyl

Janelle Sheen discussed what Alzheimer agents were included and that memantine will be reviewed at a subsequent meeting. No generics are available. There are some minor differences in pharmacokinetics. Donepezil' s kinetics are

not affected by food. Rivastigmine has minimal cytochrome P450 involvement. Due to adverse drug events and drug-drug interactions, tacrine is not commonly used in treating patients with Alzheimer's disease. Donepezil is approved as once daily dosing while the others are administered multiple times per day. Limited data exists and is mixed and additional data is required to determine if one agent is advantageous to the others. one or more brand products within the Alzheimer's class offers significant clinical advantage in general use over the generics and OTC products but is comparable to all other brands in the same class. Additionally, tacrine (Cognex®) possesses an extensive adverse effect profile. Alabama Medicaid should work with the manufacturers of the brands of donepezil, rivastigmine, and galantamine on cost proposals so that at least one brand is placed in preferred status. Brand products of tacrine (Cognex®) should not be placed in preferred status regardless of cost.

A.Z. Holloway noted that donepezil is administered once daily with food and that its side effect profile is "cleaner" than other agents. Jackie Feldman also discussed the once daily dosing and lower incidence of nausea and vomiting with donepezil. She also questioned if there is any literature that supports switching therapy in patients who do not tolerate a specific Alzheimer agent. Janelle responded that the treatment guidelines recommend alternative therapy in those who can not tolerate a specific agent without compromising efficacy. Jefferson Underwood questioned if requiring patients already stable on therapy may result in decreased cognition if therapy is switched. He also questioned if these drugs were part of the mental health drug preferred drug carve-out. Louise Jones clarified that only the antipsychotics were excluded from the preferred drug list. Jefferson Underwood stated he felt these drugs should not be part of the preferred drug list and excluded from prior authorization so patients stabilized on therapy could continue their current therapy. He also commented that for newly diagnosed patients, there should be no limitations on product selection.

Jefferson Underwood made a motion that tacrine not be place in preferred status regardless of cost and that all the other agents be placed in preferred status. The motion was seconded by Jackie Feldman. Richard Freeman asked the Board to note the recommendations and mark their ballots.

(6) PHARMACOTHERAPY REVIEWS (Refer to the web for full text reviews): Section III. Proton Pump Inhibitors (AHFS Class 562836).

<u>Product</u>
Nexium, Prevacid, Aciphex, Protonix

Janelle Sheen discussed the proton pump inhibitors (PPI) and noted that omeprazole was the only generically available PPI. Lansoprazole nine different indications while omeprazole and pantoprazole have seven and three,

respectively. Lansoprazole and omeprazole are indicated in children. All agents in this class have similar pharmacokinetics and are well tolerated. Additionally, they have similar efficacy in general use. All brand products within the class reviewed are comparable to each other and to the generics and OTC products in that class and offer no significant clinical advantage over other alternatives in general use. No brand proton pump inhibitor is recommended for preferred status.

Melanie Smith questioned what products can be opened and Janelle responded that pantoprazole and lansoprazole can be opened. Richard Freeman questioned if flavoring agents can be used with these medications. Janelle responded that there is no information in the package labeling stating that flavoring agents can not be used with any of these products. Jackie Feldman reiterated that lansoprazole and omeprazole have pediatric indications with identical age cut offs (i.e., > 2 years of age). Robert Berringer added that omeprazole may also be opened.

Richard Freeman asked the Board to mark their ballots.

Richard Freeman initiated a break at 2:20 p.m., which lasted until 2:33 p.m.

(7) PHARMACOTHERAPY REVIEWS (Refer to the web for full text reviews): Section IV. Skin and Mucous Membrane Agents (AHFS Classes 840404, 840406, 840408, 840412, 840416, 840600, 840800, 841200, 842800, 843200, 843600).

Product
Luxiq / Olux

Janelle Sheen discussed the topical antibacterials included in the review. All agents except bacitracin/neomycin combination products that contain hydrocortisone, mupirocin, clindamycin vaginal, and metronidazole vaginal are generically available. There are clinical differences between agents included in this class. For the treatment of bacterial vaginosis, the CDC recommends treating symptomatic or asymptomatic high-risk pregnant females and treatment consideration in symptomatic low-risk pregnant females. Clindamycin and metronidazole vaginal agents offer significant clinical advantage in general use over the generics and OTC products but are comparable to all other brands in this class. However, the remaining agents in the topical antibacterial class are comparable to each other and to the generics and OTC products in this class and offer no significant clinical advantage over other alternative in general use. Alabama Medicaid should work with the manufacturers of the brands of clindamycin vaginal and metronidazole vaginal on cost proposals so that at least one brand is selected as a preferred agent. In addition, there is no brand recommended for preferred status of the remaining antibacterial agents in this class.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the topical antivirals which include acyclovir and penciclovir, are indicated for the treatment of *Herpes labialis*. Additionally, acyclovir is indicated for the treatment of *Herpes genitalis* and non-life threatening mucocutaneous *Herpes simplex* virus infections in immunocompromised patients. Janelle stated that no generics are currently available and both topical antivirals are less effective than systemic therapies. The CDC guidelines genital herpes do not recommend topical products. All brand products within the topical antiviral class are comparable to each other and to the generics and OTC products in this class and offer no significant clinical advantage over other alternatives in general use. No brand topical antiviral is recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the topical antifungals and stated this class includes 18 different agents with different indications. Triple Care is now marketed as Secura Antifungal. The topical antifungal products are available in multiple dosage formulations (e.g., topical and vaginal). Topical ciclopirox has only a 5.5% cure rate. All brand products within the class reviewed are comparable to each other and to the generics and OTC products in the antifungal class and offer no significant clinical advantage over other alternatives in general use. No brand topical antifungal is recommended for preferred status.

Jackie Feldman and A.Z. Holloway questioned if Medicaid covers over-the-counter (OTC) products and if there were any OTC single-dose vaginal Candida products. Dr. Feldman discussed the importance of adherence compliance with the one-dose product. It was confirmed there are no OTC single-dose products and that Medicaid does reimburse for OTC vaginal products.

Jackie Feldman made a motion that at least one single dose vaginal antifungal product be on the preferred drug list that was seconded. Richard Freeman asked the Board to note the recommendations and mark their ballots.

Janelle Sheen discussed the scabicides and pediculocides and stated the American Academy of Pediatrics recommends permethrin as first line for lice therapy. The CDC also recommends permethrin cream as first line for lice treatment. Lindane has significant adverse drug events and the FDA provided a public health advisory warning in 2003 regarding its use and should only be used in those who can not tolerate first line therapies. The permethrin products within this class offer significant clinical advantage in general use over the other brands, generics and OTC products in the same class, but are comparable to each other. Additionally, lindane possesses an extensive adverse effect profile.
Because generic and over-the-counter permethrin products are available, no brand of permethrin is recommended for preferred status. At this time, no brand lindane product is available; however, should one become available, it should not be placed in preferred status regardless of cost.

Jefferson Underwood questioned if a lice parent educational program is in place. Mary McIntyre responded this type of program is currently not in place.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the miscellaneous local antiinfectives and stated these agents are primarily used for burn care. Ten different generic medications are included in this class and cover multiple indications. Clinical information is limited for the medications included in this class. All brand products within the miscellaneous local anti-infectives class reviewed are comparable to each other and to the generics and OTC products in this class and offer no significant clinical advantage over other alternatives in general use. No brand miscellaneous local anti-infective is recommended for preferred status.

A.Z. Holloway questioned that brand Silvadene cream is often used for burns but is not included as a preferred agent. It was clarified that this agent is generically available therefore would be available to prescribers.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the antiinflammatory agents and included that most of respective agents are available generically across all steroidal potencies. Fluticasone cream and ointment generic was approved by the FDA on May 14, 2004. Agent selection dependent upon factors such as nature, site, and extent of lesions being treated. Age and duration of treatment may also be considered. In general clinical use, there are no clinical advantages to use one equally potent antiinflammatory agent over another. All brand products within the class reviewed are comparable to each other and to the generics and OTC products in the topical anti-inflammatory agents class and offer no significant advantage over other alternatives in general use. No brand topical corticosteroid is recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the topical antipruritics which are indicated for short-term use in moderate to severe pruritus. Within this class, doxepin is the only chemical entity and is available as two different branded products. There are no clinical differences between the two products. All brands within the class reviewed are comparable to each other and to the generics and OTC products and offer no significant clinical advantage over other alternatives in general use. No brand topical antipruritic is recommended for preferred status.

Jackie Feldman questioned if any generics are available and Janelle Sheen confirmed that no generics are currently available. Jackie Feldman added that the products in this review have an advantage in the relief of itching and questioned the comparability of doxepin to other products. Janelle Sheen was unaware of any head to head trials comparing doxepin to other products. Jefferson Underwood questioned if these products are indicated for use in children. Janelle Sheen responded that the package insert does not include any specific pediatric indications. Additionally, Mary McIntyre added that the pediatric use consideration is important if the medications are on prior authorization and this drug is currently not on prior authorization and therefore there is no way to restrict its use.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the topical astringents are primarily indicated for the treatment of hyperhidrosis. Included in the class are aluminum chloride and Peruvian balsam with castor oil products. All products except for the aluminum chloride 6.5% are generically available. Mild hyperhidrosis is usually controlled with aluminum chloride 6.5% while moderate to severe cases require the 20% formulation. All brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand astringent is recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the topical keratolytics which include urea and podophyllum resin products. The podophyllum products are indicated for application by a physician in the treatment of venereal warts. Urea products are indicated for nail destruction or dissolution. All brand products in the keratolytic class are comparable to each other (the urea products and the podophyllin products) and to the generics and OTC products in this class and offer no significant clinical advantage over other alternatives in general use. No brand keratolytic is recommended for preferred status.

Jefferson Underwood questioned what agents require the least amount of physician office visits. Janelle Sheen responded that certain products are available for the treatment of venereal warts and are approved for patient application. Additionally, the CDC recommends use of the patient-applied products. Although available, these products are not part of the topical keratolytic class. Jefferson Underwood added that podophyllum may require 3 additional physician visits per year. Robert Berringer confirmed that Jefferson Underwood did not want to add podophyllum as preferred drug and added that the products that may decrease office visits were part of the topical miscellaneous skin and mucous membrane review. Jefferson Underwood was still unclear as to what products could decrease office visits and Robert Berringer stated that this question would be addressed in the topical miscellaneous skin and mucous membrane review.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the topical keratoplastic agents which include coal tar and anthralin products. Multiple formulations (e.g., liquids, ointment, creams) are available including generic products. No head to head trials have been conducted. Clinical evidence studies suggest these agents are comparable to topical corticosteroids and calcipotriol in the treatment of psoriasis. Combination therapy may be beneficial. All brand products within the keratoplastic class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand keratoplastic agent is recommended for preferred status.

Richard Freeman questioned if Janelle Sheen knew how it was discovered in 1925 that coal tar was effective in the treatment of psoriasis. Janelle Sheen offered to do additional research to find this answer.

Richard Freeman asked the Board to mark their ballots.

Janelle Sheen discussed the topical miscellaneous skin and mucous membrane agents which includes nineteen different chemical entities. Products included in this class have narrow but very different indications. Indications include wound healing, atopic dermatitis, venereal warts, and psoriasis.

When comparing agents within the topical miscellaneous skin and mucous membrane agent class, alitretinoin, becaplermin, bexarotene, collagenase, diclofenac sodium, and fibrinolysin w/desoxyribonuclease offer significant clinical advantage when used for their respective treatment indications. At this time, there is not a role for these agents in general use. Because these six medications have narrow indications with limited usage, they should be available for special needs/circumstances that require medical justification through the prior authorization process. After clinical circumstances are explored, proper medical justification will provide patient access to these agents. However, the remaining

agents in this class are comparable to each other and to the generics and OTC products in this class and offer no significant clinical advantage over other alternative in general use. No brand miscellaneous skin and mucous membrane agent is recommended for preferred status.

Jefferson Underwood questioned why podofilox was not recommended as a preferred agent although it is recommended as first line therapy in the treatment of venereal warts. Janelle Sheen answered that this specific product is generically available and is not subject to the preferred drug list. A.Z. Holloway discussed that pimecrolimus and tacrolimus are considered mainstay therapy in the treatment of atopic dermatitis in children. Janelle added that these agents are efficacious in children but have also been reported to be as effective as hydrocortisone in adult patients. Additional discussion ensued regarding age differences between pimecrolimus and tacrolimus. It was confirmed that both products are indicated in children $\geq$ 2 years of age.

A.Z. Holloway requested a motion that either pimecrolimus or tacrolimus be available for pediatric patients without any prior authorization restrictions. This motion was seconded by Jackie Feldman. Richard Freeman asked the Board to note the recommendations and mark their ballots.

(8) NEW DRUG REVIEWS (Refer to the web for full text reviews):
Eplerenone – Mineralocorticoids (Aldosterone) Receptor Antagonist (AHFS Class 402800)

Product
Inspra

Janelle Sheen discussed that this class was previously reviewed in December 2003. Spironolactone is another drug in this class which is generically available. Eplerenone is indicated for the treatment of heart failure and hypertension. The Randomized Aldactone Evaluation Study (RALES) proved aldosterone antagonism had a very important role in heart failure management. The American College of Cardiology and the American Heart Association recommends aldosterone antagonism consideration in patients with heart failure. Eplerenone was not available when this recommendation was made. One study compared eplerenone and spironolactone found similar effects on lowering blood pressure. The clinical data currently available suggests preferential use of eplerenone before spironolactone is not recommended. Additionally, hyperkalemia is as likely to occur with eplerenone as with spironolactone.

Eplerenone (Inspra®) is comparable to the other brands in this class and to the generics and OTC products in this class and offers no significant clinical advantage over other alternatives in general use. No brand of eplerenone is recommended for preferred status.

Jackie Feldman questioned if the study that compared eplerenone and spironolactone showed any differences in hospitalizations. Janelle Sheen responded that hospitalization rates were not an outcome in this specific study. Jackie Feldman also stated that the results Eplerenone Post-Acute Myocardial Heart Failure Efficacy and Survival Study (EPHESUS) are convincing regarding eplerenone use. Janelle Sheen added that additional head to head trial are needed.

Richard Freeman asked the Board to mark their ballots.
Rosuvastatin – HMG CoA Reductase Inhibitors (AHFS Class 240608)

Product
Crestor

Janelle Sheen discussed that rosuvastatin is reported as a high potency statin. Pharmacokinetic studies conducted in patients of Asian descent reported a two-fold increase in concentrations. In these patients, the package labeling includes a recommendation to initiate treatment with 5mg. Additionally, there have been reports of kidney failure and rhabdomyolysis.

Rosuvastatin is comparable to the other brands in this class and to the generics and OTC products in this class and offers no significant clinical advantage over other alternatives in general use. No brand of rosuvastatin is recommended for preferred status.

Jackie Feldman questioned if rosuvastatin had either a black box or highlighted warning in the package labeling. Janelle Sheen confirmed that neither is currently included. Jackie Feldman also voiced concern that the current PDL does not include a "high" potency statin. Dr. Underwood brought up safety with atorvastatin (Lipitor) and referred to discussion by Dr. Sydney Wolfe at the December P&T meeting. Richard Freeman noted that providers may be cautious about pushing doses of the current preferred statins and added that rosuvastatin is a good alternative.

Jackie Feldman made a motion to add rosuvastatin as a preferred drug. A.Z. Holloway seconded the motion. Richard Freeman asked the Board to note the recommendations and mark their ballots.

After the vote, additional discussion ensued about a change in Medicaid policy that permits Medicaid to accept value discount proposals at any time during the year for non-preferred drugs. Additionally, the preferred drug list may be updated on a quarterly basis but preferred drugs remain preferred for 1 year.

(9) ANTIDEPRESSANT WARNING UPDATE

Janelle Sheen discussed that amidst reports of increased suicidal thoughts with paroxetine, in June of 2003 the FDA began reviewing 25 trials of antidepressants in children. Findings included that there were no suicides reported in any of the trials, it was unclear whether certain behaviors were actual suicide attempts or self injurious behaviors, and the investigation has been complicated by a lack of standardized terminology for suicidal acts among the studies being reviewed. For example, one case where a child slapped herself in the head was classified as a suicide attempt and another case where a child stabbed himself in the neck with a pencil was classified as an accidental injury.

The FDA established an independent panel of experts in suicide assessment and adolescent suicide research, to classify the data consistently across all of the antidepressant trials in children and to establish a common set of guidelines for the interpretation of adverse events from those trials.

The results from the panel are expected by the end of the summer this year. Until the results are made public, the FDA has issued a strengthened warning for 10 common antidepressants. (fluoxetine, sertraline, paroxetine, fluvoxamine, citalopram, escitalopram, bupropion, venlafaxine, nefazodone, and mirtazapine). The warning was made to encourage observation for worsening depression or the emergence of suicidal thinking and behavior in both adult and pediatric patients taking these agents. The warning also states that discontinuation of medication may be appropriate in patients who show signs of worsening depression or suicidal behaviors or thoughts. Fluoxetine is the only drug FDA approved for use in children and adolescents for the treatment of major depressive disorder. Fluoxetine (Prozac), sertraline (Zoloft) and fluvoxamine (Luvox) are indicated for OCD in children and adolescents.

Heritage will provide updates to the agency when they are available.

(10) Pharmacy Program update was provided by Louise Jones

The Four-Brand-Limit Program is scheduled to be implemented on July 1, 2004. Within a calendar month, patients may get up to four branded medications. Long-term care residents and children (i.e., recipients $\leq$ 20 years of age) will be excluded from this program. Antipsychotics and antiretrovirals are limited up to ten medications per month. In no case can the brand limit exceed 10 medications per month. No overrides will be permitted. A subcommittee is evaluating additional exclusions.

Tiered Copays are scheduled for a Fall of 2004 implementation. Preferred generics, nonreviewed generics and over-the-counter medications will have no copay. Preferred drug products will have a $1.00 copay. Non-preferred brand and nonreviewed brand products will have a $3.00 copay. Pharmacies can not

withhold medications in cases where patients are unable to pay the respective copays.

Medicaid will be implementing an electronic prior authorization system through HID named Rx Expert. It is estimated this program will eliminate 40% of the calls to the call center. It will evaluate both pharmacy and medical claims data to make a determination. It is expected to take about 4 seconds to approve therapy. This program is scheduled for a Fall 2004 implementation.

The narcotic analgesic will be added to the therapeutic duplication edit. It will not include the sustained release opiates.

The State has reported state savings of $7.3 million and $22.0 million total savings from the PDL. These savings do not consider the supplemental rebate savings. Effects of the PDL implementation on medical utilization and costs are being monitored and results will be presented at the next P&T meeting.

Medicaid is working with Blue Cross Blue Shield and InfoSolutions to provide PDA's to provider and provide access to patient pharmacy records. This system also provides therapy suggestions/alternatives. This project is scheduled for a Fall 2004 implementation.

Medicaid will be providing the P&T Committee members with CME/CE credits for review of the drug class reviews.

Additional rule changes include prior authorization of generic medications that are high cost or have abuse potential.

Medicaid received an additional $144 million in funding.

11) Results of the Balloting

A. The P&T Committee voted unanimously to accept the recommendation that no brand α-Glucosidase Inhibitor is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Mary McDougall MD
Medical Director — ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Kathy Daly
Deputy Commissioner — ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Carol A. Hermann RN
Commissioner — ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

B. The P&T Committee voted to accept the amended recommendation that brand metformin extended release is recommended for preferred status. Medicaid should accept brand metformin extended release for preferred status.

Medical Director ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Deputy Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

C. The P&T Committee voted unanimously to accept the recommendation that at least one brand insulin product is recommended for preferred status. Medicaid should accept cost proposals so that at least one brand is selected as a preferred agent.

Medical Director ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Deputy Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

D. The P&T Committee voted to accept the recommendation that no brand meglitinide is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Deputy Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

E. The P&T Committee voted unanimously to accept the recommendation that no brand sulfonylurea product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Deputy Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

F. The P&T Committee voted unanimously to accept the recommendation that Medicaid should work with manufacturers of the recommended brands of thiazolidinediones, pioglitazone (Actos) and rosiglitazone (Avandia), on cost proposals so that at least one of the recommended brands is selected as a preferred agent. Medicaid should accept cost proposals from manufacturers to determine cost effective products so that as least one of the recommended products is placed in preferred status.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

G. The P&T Committee voted unanimously to accept the recommendation that no brand antidiabetic combination agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

H. The P&T Committee voted to accept the amended recommendation that brand donepezil, rivastigmine, and galantamine be recommended for preferred status. Medicaid should accept brand donepezil, rivastigmine, and galantamine for preferred status. Brand tacrine should not be given preferred status regardless of cost.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

I. The P&T Committee voted to accept the recommendation that no brand proton pump inhibitor product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

J. The P&T Committee unanimously voted to accept the recommendation that Medicaid should work with manufacturers of the recommended brands of antibacterial agents, clindamycin vaginal and metronidazole, on cost proposals so that at least one of the recommended brands is selected as a preferred agent. Medicaid should accept cost proposals from manufacturers to determine cost effective products so that as least one of the recommended products is placed in preferred status.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

K. The P&T Committee voted unanimously to accept the recommendation that no brand topical antiviral is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

L. The P&T Committee voted to accept the amended recommendation that at least one single dose vaginal antifungal product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Deputy Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

M. The P&T Committee voted unanimously to accept the recommendation that no brand scabicide and pediculicide product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Deputy Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

N. The P&T Committee voted to accept the recommendation lindane products possesses an extensive adverse effect profile or is clinically inferior to the other brand, generics and OTC products. Lindane should not be given preferred status regardless of cost.

Medical Director ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Deputy Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

Commissioner ☐ Approve ☐ Deny ☐ Approve with modification ☒ Table for future review

O. The P&T Committee voted unanimously to accept the recommendation that no brand miscellaneous local anti-infective products are recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

P. The P&T Committee voted unanimously to accept the recommendation that no brand topical corticosteroid is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

Q. The P&T Committee voted unanimously to accept the recommendation that no brand topical antipruritic agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

R. The P&T Committee voted unanimously to accept the recommendation that no brand astringent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

S. The P&T Committee voted unanimously to accept the recommendation that no brand keratolytic agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

T. The P&T Committee voted unanimously to accept the recommendation that no brand keratoplastic agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

U. The P&T Committee voted to accept the amended recommendation that either pimecrolimus (Elidel) or tacrolimus (Protopic) is recommended for preferred status in pediatric patients. Medicaid should accept cost proposals so that at least one brand is selected as a preferred agent in pediatric patients. or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner				
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

V. The P&T Committee voted to accept the recommendation that no brand eplerenone is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

W. The P&T Committee voted to accept the amended recommendation that rosuvastatin is recommended for preferred status. Medicaid should accept rosuvastatin for preferred status.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

(12) Louise Jones stated that the next Pharmacy and Therapeutics Committee meeting will be August 11, 2004.

(13) Meeting was adjourned at 5:12 p.m.

Respectfully submitted.

Janelle N. Sheen 6-14-2004

Janelle Sheen Date